

DEC 17 2003

K033052 (pg 1 of 1)

V. 510(k) SUMMARY

Submitted by: Compumedics USA, Ltd.
7850 Paseo Del Norte
El Paso, TX 79912

Contact Person: Elvira Garcia

Date Prepared: September 24, 2003

Proprietary Name: Quik Gel, EEG Electrodeconductive Gel

Common Name: QuikGel®

Classification Name: Electroconductive Media

Predicate Devices: Conductive Gel
K022006

TEN20 Conductive
K883149

Description of the Device: A jellylike mass consisting of salts combined with carbohydrate thickening agent, hypo-allergenic organic emollient, anti-fungal agents all in a aqueous solvent.

Intended Use of the Device: The Quik Gel® is intended for use when a reduction of skin impedance would enhance a test result. It also helps the Quik Cap electrodes adhere to the patient.

Technological Characteristics: The Quik-Gel® has the same technological characteristics as the predicate device.

Conductive Gel K022006
TEN20 Conductive K883149



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2003

Ms. Elvira Garcia
Quality Assurance Manager
Compumedics USA, Ltd.
7850 Paseo Del Norte
El Paso, Texas 79912

Re: K033052
Trade/Device Name: Quik Gel
Regulation Number: 21 CFR 882.1275
Regulation Name: Electroconductive media
Regulatory Class: II
Product Code: GYB
Dated: September 24, 2003
Received: September 29, 2003

Dear Ms. Garcia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033052

Device Name: Quik Gel

Indications For Use: The Quik gel is intended to enhance electrical conductivity by facilitating transmission of the electrophysiological signals from the patient to the equipment to reduce impedance at the electrode-to-skin interface. It also helps the Quik cap electrodes adhere to the patient.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033052